

Why is this study being done?



This study is being done to learn more about a medicine called dupilumab for treating PN in children. Dupilumab is already authorized in the United States and the European Union for the treatment of adults with PN, and in multiple countries/regions for children with asthma, atopic dermatitis, and eosinophilic esophagitis.

The aim of the study is to evaluate the safety and pharmacokinetics of dupilumab in children with PN. Pharmacokinetics uses blood tests to study what happens to a drug in the human body.

Who can be in the study?



The study will include children who:

- Are 6 months to 17 years of age (before 18th birthday),
- AND
- Have been diagnosed with PN,
- OR
- Have symptoms of PN with presence of pruritic and firm nodules that have not been relieved with topical treatments (topical calcineurin inhibitor [TCI], topical steroids [TCS]).

There are additional requirements for participation that the study staff will explain to you.

Thank you for your interest in this research. *We could not do it without you.*



Research studies, also called clinical studies, test how well new medical approaches work in people. Every approved medicine and vaccine we have today was tried and tested in a research study. By taking part in this study, you and your child can help improve treatment for children with PN.

PN is a very itchy skin condition. It's hard for children to stop rubbing and scratching the spots, which leads to hard, crusty bumps and more rubbing and scratching.

This brochure will explain the study. If you are interested in learning more, talk to the study staff. They are happy to answer any questions you have.

With much appreciation,

The *Liberty PN-PRIME Kids* Study Team

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Protocol Level
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The Liberty PN-PRIME Kids Study



A research study for
children with prurigo
nodularis (PN)

sanofi

LIBERTY
PN PRIME-Kids

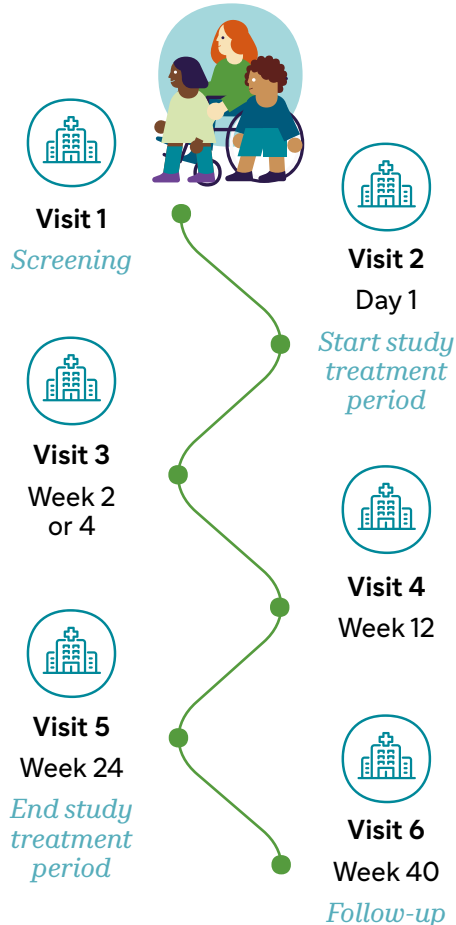


How long is the study?

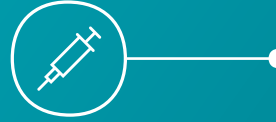
The study lasts approximately 42 to 44 weeks (about 11 months). It includes 3 periods:

- *Screening period:* 2 to 4 weeks (about 1 month)
- *Treatment period:* 24 weeks (6 months)
- *Follow-up period:* 16 weeks (4 months)

You and your child will need to visit the study clinic 6 times.



What treatment would my child receive?



All children in this study will receive the study medicine, a drug called dupilumab. It will be given during the treatment period as an injection under the skin every 2 or 4 weeks (at home or onsite).

What happens during the study?



Physical exam



Vital signs



Pregnancy test (if applicable)



Blood tests



Urine test



Electrocardiogram heart test

Your child will have tests and health checks to see if he/she is eligible for the study. Some of these tests and health checks will be repeated at study clinic visits. Blood will be taken at each of the 6 study visits.



You or your child will be asked to rate his/her itchiness level daily. The study staff will lend you an electronic device for recording your answers every day.

Do study participants get paid?



The study medicine and all study-related procedures are provided at no cost to you. Reimbursement for reasonable expenses (such as parking, meals, and travel) may be available. Talk to the study staff to learn more.

What else should I know?



If you and your child are interested in joining the study, you'll be asked to read and sign an Informed Consent Form. Please ask about anything you do not understand. The study staff is happy to answer any questions.